

REMARKS

Claims 1-51 are pending in the application. Claims 1-51 have been rejected. Claims 1, 22, 33, 42, 47 and 51 have been amended. No new matter has been added.

Claim Amendments

Claim 1 and 22 have been amended to recite integrated electronic instrumentation for generating an electronic record containing information regarding use of the paper diary. Claim 33 has been amended to recite that the steps of detecting, capturing and storing are performed using electronic instrumentation incorporated into the instrumented paper diary. Claim 42 has been amended to recite that the step of generating an electronic record is performed using electronic instrumentation incorporated into the paper diary. Claim 47 has been amended to recite that the step of tracking is performed using electronic instrumentation incorporated into the instrumented paper diary. Claim 51 has been amended to recite the step of incorporating said electronic instrumentation into the paper diary to record when the diary is in use. The support for these amendments can be found in the figures and specification of the application.

Claim Rejections - 35 U.S.C. §102

The Examiner has maintained the rejection of claims 1-32 and 51 under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 6,362,440 (“Karidis”). The Examiner has also maintained the rejection to claims 33, 38, and 39 under 35 U.S.C. 102(b) as being anticipated by Straka et al; Patient Self Reporting of Compliance Does not Correspond with Electronic Monitoring: An Evaluation Using Isosorbide Dinitrite as a Model Drug (“Straka”).

Claims 1, 22, and 51

Claims 1, 22, and 51 have been amended in this response to clarify and reinforce that the claims 1, 22, and 51 are directed to an “instrumented paper diary.” That is, the electronic instrumentation is integrated or incorporated into the paper dairy for generating an electronic record containing information regarding use of the paper diary. Applicants believe this amendment addresses the Examiners concern that “applicant does not claim the electronic instrument added to the paper diary”

Karidis is directed to a portable computer with a recording device. This is not the same as the claimed “instrumented paper diary” wherein the electronic instrumentation is integrated or incorporated into the paper diary for generating an electronic record containing information regarding use of the paper diary. One advantage of such an “instrumented paper diary” is the integrated or incorporated electronic instrumentation may be unobtrusive so that a user records data in the paper diary without necessarily being aware the usage is being monitored. That is, the electronic instrumentation doesn’t interfere with the normal usage of the paper diary. In contrast a user of the device of Karidis would be very aware of the device being a portable computer (it has a display) and is imputing information into the portable computer and not a paper diary.

As such, Karidis fails to disclose each and every element of amended claims 1, 22, and 51. Specifically Karidis fails to disclose electronic instrumentation that is integrated or incorporated into the paper diary as set forth in claims 1, 22, and 51.

In light of the foregoing arguments, Applicants respectfully submit that amended claims 1, 22 and 51 are patentable over Karidis. Applicants therefore request the Examiner withdraw the rejections of amended claims 1, 22, and 51 under 35 U.S.C. §102, and pass the claim to allowance.

Claims 2-21 and 23-32

Claims 2-21 depend from amended claim 1 and claims 23-32 depend from amended claim 22. As such, claims 2-21 and 23-32 incorporate each and every element of amended claims 1 and 22 respectively. As set forth above, Karidis fails to disclose each and every element of amended claims 1 and 22. Therefore Karidis fails to disclose each and every element of claims 2-21 and 23-32.

In light of the foregoing arguments, Applicants respectfully submit that claims 2-21 and 23-32 are patentable over Karidis. Applicants therefore request the Examiner withdraw the rejections of claims 2-21 and 23-32 under 35 U.S.C. §102, and pass the claims to allowance.

Claim 33

Claim 33 has been amended to recite a method of monitoring subject compliance, comprising: detecting an event related to data entry in a paper diary for recording data using electronic instrumentation incorporated into the paper diary; and capturing and storing a characteristic of the event to generate an electronic record of said data entry using the electronic instrumentation incorporated into the paper diary.

Straka fails to disclose each and every element of claim 33. Straka discloses monitoring the use of the vial that holds the medicine in the study. The MEMS vial in Straka only detects the opening and closing of the vial itself it does not detect the use of the paper diary using the electronic instrumentation incorporated into the paper diary. The MEMS vial cannot determine when a data entry is made in the paper diary. Using the methodology of Straka cannot detect proactive or retroactive data entry in a diary because it detects the usage of the vial not the diary. In contrast, the present invention tracks the usage of the diary and allows for the detection of such proactive or retroactive data entry. This is discussed as one of the advantages of the present invention (See Background of the Invention).

In light of the foregoing arguments, Applicants respectfully submit that amended claim 33 is patentable over Straka. Applicants therefore request the Examiner withdraw the rejection of claim 33 under 35 U.S.C. §102, and pass the claims to allowance.

Claims 38 and 39

Claims 38 and 39 depend from claim 33. As such, claims 38 and 39 incorporate each and every element of amended claim 33. As set forth above, Straka fails to disclose each and every element of amended claim 33. Therefore Straka fails to disclose each and every element of claim 38 and 39.

In light of the foregoing arguments, Applicants respectfully submit that claims 38 and 39 are patentable over Straka. Applicants therefore request the Examiner withdraw the rejection of claims 38 and 39 under 35 U.S.C. §102, and pass the claims to allowance.

Claim Rejections - 35 U.S.C. §103

The Examiner has maintained the rejection to claims 34-37, 40, and 41 under 35 U.S.C. §103(a) as being unpatentable over Straka in view of Karidis. The Examiner has also maintained the rejection to Claims 42-50 under 35 U.S.C. §103(a) as being unpatentable over Hyland et al: Diary Keeping in Asthma: Comparison of written and Electronic methods (“Hyland”); further in view of Karidis. Applicant respectfully traverses the rejection for the following reasons.

Claims 34-37, 40, and 41

Claims 34-37, 40, and 41 all depend from amended claim 33 and as such incorporate each and every element of claim 33. As previously argued, Straka fails to teach or suggest each and every element of amended claim 33. Specifically, Straka fails to teach or suggest detecting an event related to data entry in a paper diary for recording data using electronic instrumentation incorporated into the paper diary; and capturing and storing a characteristic of the event to generate an electronic record of said data entry using the electronic instrumentation incorporated into the paper diary. Straka teaches monitoring the use of the vial that holds the medicine in the study. The MEMS vial in Straka only detects the opening and closing of the vial itself it does not detect the use of the paper diary. The MEMS vial cannot determine when a data entry is made in the paper diary using the electronic instrumentation incorporated into the paper diary. Using the methodology of Straka cannot detect proactive or retroactive data entry in a diary because it detects the usage of the vial not the diary. In contrast, the present invention tracks the usage of the diary allows for the detection of such proactive or retroactive data entry. Furthermore, Straka clearly set forth that the people being monitored were informed of what the vial did (monitor use). In contrast, one of the advantages of the present invention is that it is unobtrusive so that the diary user need not even be aware of the monitoring. Thus, Straka fails to teach or suggest each and every element of claim 33. The addition of Karidis fails to cure this deficiency. As discussed above, Karidis makes no mention whatsoever of an instrumented paper diary. As such, Karidis does not teach or suggest the recording of use of a paper diary using the electronic instrumentation incorporated into the paper diary. Thus neither Straka nor Karidis,

alone or combined, teach or suggest each and every element of claim 33. As claims 34-37, 40, and 41 all depend from amended claim 33, neither Straka nor Karidis teach or suggest each and every element of claims 34-37, 40, and 41.

In light of the foregoing claim amendments and arguments, Applicants respectfully submit that claims 34-37, 40, and 41 are patentable over Straka and Karidis. Applicants therefore request the Examiner withdraw the rejections of claims 34-37, 40, and 41 under 35 U.S.C. §103, and pass the claims to allowance.

Claim 42

Claim 42 has been amended to recite a method of confirming data obtained in a clinical trial, comprising generating an electronic record containing information regarding use of a paper diary for recording clinical trial data using electronic instrumentation incorporated into the paper diary; and comparing said electronic record with written clinical trial data in the paper diary.

Applicants assert that Hyland fails to teach or suggest each and every element of amended claim 42. Amended claim 42 is directed to a method of monitoring compliance by tracking paper diary use using electronic instrumentation incorporated into the paper diary. The study of Hyland involved the participants making two separate diary entries: one paper diary and one computer diary. The electronic records of the use of the paper diary were not generated using electronic instrumentation incorporated into the paper diary. Usage was only tracked on the computer, not the paper diary. Combining the two methods of data entry (paper and computer) would have undermined the whole purpose of the study (comparing the two methods). Furthermore, as discussed above, Karidis makes no mention of an instrumented paper diary of the present invention. The device of Karidis is effectively the computer log in the Hyland study. Thus the combination of Karidis with Hyland does not cure the deficiencies of Hyland. As such neither Hyland nor Karidis alone or in combination teach or suggest each and every element of amended claim 42.

In light of the foregoing claim amendments and arguments, Applicants respectfully submit that amended claim 42 is patentable over Hyland and Karidis. Applicants therefore

request the Examiner withdraw the rejection of amended claim 42 under 35 U.S.C. §103, and pass the claim to allowance.

Claims 43-46

Claims 43-46 depend from amended claim 42. As such claims 43-46 incorporate each and every element of claim 42. As discussed above the combination of Hyland and Karidis fails to teach or suggest each and every element of amended claim 42. Thus, the combination of Hyland and Karidis fails to teach or suggest each and every element of claims 43-46.

In light of the foregoing claim amendments and arguments, Applicants respectfully submit that claims 43-46 are patentable over Hyland and Karidis. Applicants therefore request the Examiner withdraw the rejection of claims 43-46 under 35 U.S.C. §103, and pass the claims to allowance.

Claim 47

Claim 47 has been amended to recite A method of monitoring subject compliance in a clinical trial, comprising providing a subject with an instrumented paper diary for recording clinical trial data; and tracking the subject's use of the instrumented paper diary using electronic instrumentation incorporated into the instrumented paper diary.

Applicants assert that Hyland fails to teach or suggest each and every element of amended claim 47. There is no use of an instrumented paper diary incorporating electronic instrumentation for tracking use of the instrumented paper diary in Hyland. The study of Hyland involved the participants making two separate diary entries: one paper diary and one computer diary. Usage was only tracked on the computer, not the paper diary. Combining the two methods of data entry (paper and computer) would have undermined the whole purpose of the study (comparing the two methods). Furthermore, as discussed above, Karidis makes no mention of an instrumented paper diary. The device of Karidis is effectively the computer log in the Hyland study. Thus the combination of Karidis with Hyland does not cure the deficiencies

of Hyland. As such neither Hyland nor Karidis alone or in combination teach or suggest each and every element of amended claim 47.

In light of the foregoing claim amendments and arguments, Applicants respectfully submit that claim 47 is patentable over Hyland and Karidis. Applicants therefore request the Examiner withdraw the rejection of claim 47 under 35 U.S.C. §103, and pass the claim to allowance.

Claims 48-50

Claims 48-50 depend from amended claim 47. As such claims 48-50 incorporate each and every element of claim 47. As discussed above the combination of Hyland and Karidis fails to teach or suggest each and every element of amended claim 47. Thus, the combination of Hyland and Karidis fails to teach or suggest each and every element of claims 48-50.

In light of the foregoing claim amendments and arguments, Applicants respectfully submit that claims 48-50 are patentable over Hyland and Karidis. Applicants therefore request the Examiner withdraw the rejections of claims 48-50 under 35 U.S.C. §103, and pass the claims to allowance.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in condition for allowance. Accordingly, the Examiner is respectfully requested to pass this application to issue. If, however, the Examiner considers that further obstacles to allowance of these claims persist, we invite a telephone call to Applicant's representative.

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Respectfully submitted,

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